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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,520	12/10/2001	Neil David Hammond Raven	1581.081000/RWE	4276

7590 02/09/2004

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EXAMINER

DAVIS, DEBORAH A

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/889,520

Applicant(s)

RAVEN ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-11 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 12-18 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6,9-11 and 19 is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1, claims 1-6, 9-11 and 19 in Paper No. 16 is acknowledged. Applicant traverses restriction of Group I on the basis that a serious burden would not be imposed on the Examiner if restriction were not required because search for one group of claims are likely to encompass the search for the other groups even if the groups are found independent and distinct. This argument is not found persuasive because the requirement for restriction under 371 is to determine if inventions or groups of inventions form a single general inventive concept under PCT Rule 13.1. In the instant case, Groups 1-3 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature tying the three groups together, as communicated in the previous action. Therefore, restriction is maintained and made final.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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4. Claim 1 recites "associating the analyte with a thermostable reporter kinase" is vague because it is unclear if a complex is being formed. Also, in line 3, "reporter kinase" is confusing because it is unclear if this kinase is the same as the thermostable reporter kinase. Please clarify. Claim 1 also recites that endogenous kinase is inactivated by heat; how does the heat affect the other reagents in the assay? How is the analyte detected ?

5. In claim 4, do the reporter adenylate kinase bind the analyte, antibody or both, the binding relationship is unclear. When the reporter adenylate kinase associated with the analyte is exposed to ADP, how do these reagents bind? Please clarify.

6. Claim 9 recites "determining the presence and/or amount of detector composition that has bound to analyte by adding a substrate for the thermostable enzyme" is vague because it is unclear how the presence of the detector composition is determined by the addition of a substrate. How do these reagents interact?

Allowable Subject Matter

7. Claims 1-6, 9-11 and would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

8. Claim 19 allowed.

9. The following is an examiner's statement of reasons for allowance: The method steps of washing to remove endogenous non-thermostable and thermostable reporter

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kinase not specifically associated with the analyte followed with the step of heating to inactivate endogenous non-thermostable kinase not removed by washing is not found in the prior art and is unobvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

A. Murakami et al teaches a bioluminescent enzyme immunoassay using thermostable mutant luciferase and acetate kinase as a labelled enzyme, (Analytica Chimica Acta, 361, (1998), pages 19-26)

B. Atkinson et al (USP#4,385,120) teaches a thermostable glycerokinases and process for its production.

C. Zeikus et al (USP#4,628,031) teaches a thermostable starch converting enzymes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

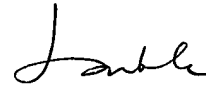
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.



Deborah A. Davis
CM1, 7D16
January 24, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
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01/27/04